Chapter HFS 116

BIRTH AND DEVELOPMENTAL OUTCOME MONITORING PROGRAM

Note: Chapter HSS 116 was renumbered ch. HFS 116 under s. 13.93 (2m) (b) 1., Stats., and corrections were made under s. 13.93 (2m) (b) 6. and 7., Stats, Register, May, 1998, No. 509.

HFS 116.01 Authority and purpose. This chapter is promulgated under the authority of ss. 253.12 (4) and 227.11 (2), Stats., to implement the birth and developmental outcome monitoring program established by s. 253.12, Stats. The purpose of the program is to provide for:

(1) Reporting to the department of information about adverse neonatal outcomes, birth defects, developmental disabilities and other severe disabilities in children from birth to age 6;

(2) Analysis by the department of that information;

(3) Dissemination by the department of that information in an aggregate, non−identifying form for public policy formulation and epidemiological research uses; and

(4) Release by the department of that information in a form that specifically identifies a child, but only to the following persons and agencies:

(a) The reporting physician or nurse to verify the information;

(b) On request, to the Wisconsin department of public instruction to ensure that the child receives services;

(c) On request and with the informed consent of the parent or guardian, to the local public health officer for follow−up care or for purposes of a health, demographic or epidemiological investigation;

(d) On request and with the informed consent of the parent or guardian, to a representative of a federal or state agency for performance of a legally authorized function, but without the name or address of the child; and

(e) To a researcher who has the informed consent of the parent or guardian.

History: Cr. Register, September, 1989, No. 405, eff. 10−1−89; corrections in (intro.) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

HFS 116.02 Applicability. This chapter applies to:

(1) The department;

(2) A physician who is the primary treating physician of a child and who makes a diagnosis or suspects with reasonable medical certainty that the child has a reportable condition;

(3) A nurse when no physician has treated the child who, upon visiting the child, knows or suspects with reasonable medical certainty that the child has a reportable condition;

(4) Local public health officers who request reportable information from the department about a child;

(5) The Wisconsin department of public instruction when that agency requests reportable information from the department;

(6) Any other state agency or any federal agency that requests reportable information from the department;

(7) A child on whom reportable information is collected, maintained and disclosed by the department; and

(8) The parent or guardian of the child on whom reportable information is collected, maintained and disclosed by the department.

History: Cr. Register, September, 1989, No. 405, eff. 10−1−89.

HFS 116.03 Definitions. In this chapter:

(1) "Adverse neonatal outcome" has the meaning prescribed in s. 253.12 (1) (a), Stats., namely, one of the following resulting to a child at birth or in the first month following birth:

(a) Birth weight of less than 2,500 grams;

(b) A condition of a chronic nature, including central nervous system hemorrhage or infection of the central nervous system, which may result in a need for long−term care; or

(c) An Apgar score of 3 or less at 5 minutes following birth.

(2) "Apgar score" has the meaning prescribed in s. 253.12 (1) (b), Stats., namely, a numerical expression of the condition of a newborn infant which is the sum of points achieved after assessing the infant's heart rate, respiratory effort, muscle tone, reflex irritability and color.

(3) "BDOMP report form" means the format provided by the department for the purpose of reporting adverse neonatal outcomes, birth defects, developmental disabilities and other severe disabilities.

(4) "Birth and developmental outcome monitoring program" or "BDOMP" means the program established by s. 253.12, Stats.

(5) "Birth defect" has the meaning prescribed in s. 253.12 (1) (c), Stats., namely, one or more of the following conditions resulting to a child:

(a) A structural deformation, being a primary structural defect that results from a localized error of morphogenesis;

(b) A developmental malformation, being an alteration in shape and structure or of the shape or structure of a previously normally formed part; or

(c) A genetic, inherited or biochemical disease.

(6) "Case" means a child determined to have a particular adverse neonatal condition, birth defect, developmental disability or other severe disability on the basis of clinical or laboratory criteria or both.

(7) "Center" means the department's center for health statistics.

(8) "Child" has the meaning prescribed for "infant or child"in s. 253.12 (1) (c), Stats., namely, a human from birth to the age of 6.

(9) "Department" means the Wisconsin department of health and family services.

(10) "Developmental disability" means a disability attributable to brain injury, cerebral palsy, epilepsy, autism, mental retardation or another neurological condition closely related to mental retardation or requiring treatment similar to that required for mental retardation, which has continued or can be expected to continue indefinitely and constitutes a substantial handicap to the afflicted individual.

(11) "Guardian" has the meaning prescribed in s. 48.02 (8), Stats.

(12) "Informed consent" means the written consent of a parent or guardian for disclosure of information from BDOMP data.

(13) "Local health officer" or "officer" has the meaning prescribed in s. 250.01 (5), Stats.

(14) "Neonatal death" means a live born infant who dies before completing 28 days of life.

(15) "Normal variant" means a condition which is not reportable because it appears in Appendix A.

(16) "Nurse" means a person licensed as a nurse under ch. 441, Stats.

(17) "Other severe disability" has the meaning prescribed in s. 253.12 (1) (g), Stats., namely, a severe sensory impairment, severe physical handicap or developmental delay that results from injury, infection or disease, is chronic in nature and requires long−term care.

Note: 1999 Wis. Act 114 repealed s. 253.12 (1) (g), Stats.

(18) "Parent" has the meaning specified under s. 48.02 (13), Stats.

(19) "Primary treating physician" means a person licensed to practice medicine or osteopathy under ch. 448, Stats., who is the first physician to diagnose or suspect a reportable condition or to diagnose or suspect a change in a reportable condition.

(20) "Reportable condition" means an adverse neonatal outcome, a birth defect, a developmental disability or any other severe disability.

(21) "Suspected case" means a child who, on the basis of recognized medical testing and evaluation, is thought to have a particular adverse neonatal condition, birth defect, developmental disability or other severe disability, but the results of the testing and evaluation are not conclusive.

History: Cr. Register, September, 1989, No. 405, eff. 10−1−89; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; **correction in (8) made under s. 13.93 (2m) (b) 7., Stats**.

HFS 116.04 Reporting of severe disabilities. (1) CONDITIONS REQUIRING A REPORT. (a) A report shall be submitted to the department on a child who has any of the following conditions:

1. A birth weight of less than 2500 grams;

2. A condition, including central nervous system hemorrhage or infection of the central nervous system, which may result in need for long−term care;

3. At 5 minutes following birth, an apgar score of 3 or less;

4. A structural deformation;

5. A developmental malformation;

6. A genetic, inherited or biochemical disease;

7. A developmental disability;

8. An impairment of hearing or sight resulting from injury, infection or disease, which is likely to require long−term care;

9. A physical impairment resulting from injury, infection or disease, which is likely to require long−term care; or

10. Delayed development due to an injury, infection or disease, which is likely to require long−term care.

(b) A normal variant when occurring alone does not require a report.

(c) A report shall be submitted for a child who is diagnosed on or after July 1, 1989, as having a reportable condition.

(2) RESPONSIBILITY FOR REPORTING. (a) The physician who is the primary treating physician for a child and who makes a diagnosis of a reportable condition in the child, or a nurse if no physician has treated the child, shall report the condition to the center within 60 days after making the diagnosis or determination or suspecting with reasonable medical certainty that a child has a reportable condition. The report shall be made in a format prescribed by the department. When revising the report form, the department shall consult with representatives of data providers, including the Wisconsin hospital association and the Wisconsin state medical society, as well as data users.

Note: For copies of the BDOMP reporting format, contact Department of Health and Family Services, Center for Health Statistics, P.O. Box 309, Madison, WI 53701−0309, (608) 267−7168.

(b) A new report shall be submitted on a case whenever there is a new diagnosis or determination of a condition or a change in the condition related to the birth defect, adverse neonatal outcome or developmental or other severe disability.

(c) If a child is diagnosed as having, or is suspected of having, an adverse neonatal outcome in the form of a weight of under 2,500 grams at birth or an Apgar score of under 3 at 5 minutes after birth, with no other condition reportable under this chapter, a birth certificate which indicates the presence of this condition, properly completed and filed with the state registrar, shall constitute a report for purposes of this chapter.

(d) If a neonatal death occurs with no other condition reportable under this chapter or when the diagnosis is a normal variant if occurring alone, no BDOMP report is required.

(3) REPORT CONTENT AND FORMAT. (a) Each report of a case or suspected case shall include identifying, diagnostic, causative if known, systemic, notification and referral information. The diagnostic information shall include type of outcome or abnormality.

(b) Reports shall be submitted in writing or electronically on a magnetic diskette or magnetic tape. The center shall specify the physical specifications for the data submittal media and a recommended format for data submission.

(4) TIMELINESS OF REPORTS. A report shall be submitted to the center within 60 days after a diagnosis or determination is made of the condition or, in the absence of a diagnosis or determination, the condition is suspected with reasonable medical certainty.

(5) HANDLING OF REPORTS. (a) All reports shall be sent to the center. The center shall review reports for completeness and accuracy, merge duplicate reports and query reporting sources to substantiate unusual data, resolve differences between inconsistent data and obtain missing or incomplete data.

(b) All data revisions required as a result of the reviews performed under par. (a) shall be corrected by the data provider and resubmitted to the center within 10 working days after receipt of the notification of unacceptable data.

(c) The center shall code and enter data from the reports and shall produce an annual report and summary tabulations and distribute them in accordance with s. 253.12 (3) (b) and (c), Stats., and to other data users in strict adherence to the confidentiality requirements specified in s. 253.12 (5), Stats., and s. HFS 116.05.

History: Cr. Register, September, 1989, No. 405, eff. 10−1−89; corrections in (5) (c) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

HFS 116.05 Confidentiality. (1) RELEASE OF INFORMATION. (a) The department shall keep birth and developmental outcome monitoring reports confidential and may release information from them only in accordance with s. 253.12 (5), Stats., and following the procedures in sub. (2).

(b) No summary tabulation in which birth and developmental outcome monitoring information is released by the department may contain any child−identifiable data.

(2) ACCESS TO INFORMATION. (a) The department may only release child−identifiable data as follows:

1. To the parent or guardian of a child on whom a report was submitted. The center shall send the requested information to the parent or guardian within 10 days following receipt of a written request. The center may require verification of the identity of the requester;

2. To the local health officer for the place of residence of a child whose condition has been reported, upon a written request for information. The local health officer may only receive information with the informed consent of the parent or guardian and may only receive and disclose information in order to render or coordinate necessary follow−up care or to conduct a health, demographic or epidemiological investigation. The center shall acknowledge the request within 10 days after receiving it and shall furnish the requested information by the tenth day of the month

following receipt of the information under s. HFS 116.04 (1). The center shall submit information to the officer once the informed consent of the parent or guardian of the child identified is obtained by the center. The furnished information shall be in either written or electronic form. The center shall notify the parent or guardian that the information is being released to the local health officer and the purpose for which it is released on the same day that the information is released. The local public health officer shall destroy the information received no later than 365 days after receiving it;

3. To the division of handicapped children and pupil services of the Wisconsin department of public instruction, upon written request. This information may only be used to ensure that necessary services are provided to the child. The center shall give information to the division of handicapped children and pupil services under the terms of a written agreement between the division and the center. The information shall be in either written or electronic form. The center shall notify the parent or guardian that the information is being released to the division of handicapped children and pupil services on the same day that the information is released to that division;

4. To a reporting physician or nurse for the purpose of verifying information reported by the physician or nurse; and

5. To any person requesting information in writing for purposes of legitimate demographic, epidemiological, health or social services research. The center shall furnish the requested information to the researcher only if the informed, written consent of the parent or guardian of the child is obtained by the center. The center shall review the nature and purpose of a request. The center shall consult with qualified professionals in the course of its review. The center shall acknowledge the request within 10 days after receiving it, review it for approval and, if approved, furnish the information within 30 days after receipt of the request except that if there is a delay in verifying a request, the center shall notify the requester of the delay and when the data will be furnished if the request is approved. The center shall notify the parent or

guardian that the information is being released to the requester and the purpose for which it is released on the same day that the information is released to the requester.

(b) Any informed consent of the parent or guardian required under this subsection shall be in writing and shall contain the name of the requester, the name of the child whose record is to be disclosed, the purpose of or need for the disclosure, the specific information to be disclosed, the time period for which the consent is effective, the date on which the consent document is signed and the signature of a parent or guardian.

(c) The department may release child−identifiable information that does not include the child's name or address to a representative of a federal or state agency performing a legally authorized function of that agency upon written request of the agency. This information shall be disclosed only as necessary to perform the legally authorized function of the agency. The center shall review and approve specific requests by an agency for child−identifiable data to fulfill its statutory mandate. In its written request, the agency shall provide the center with written statutory evidence that the agency is performing its legally authorized function when using the requested data from the center. The information shall be in either written or electronic form. The center shall notify the parent or guardian that the information is being released to the agency and the purpose for which it is released on the same day the information is released to the agency.

(3) CHARGES FOR REQUESTED INFORMATION. The center shall charge all requesters the total actual and necessary costs of producing the requested information, obtaining the informed consent of the parent or guardian and informing the parent or guardian of the release of the information.

(4) DATA DESTRUCTION. Not later than 10 years after receiving a report under s. HFS 116.04, the department shall delete from its files the name of the child contained in the report.

History: Cr. Register, September, 1989, No. 405, eff. 10−1−89; correction in (1) (a) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.